

JAN 11 2001

K003273  
10/2

## 510 (K) Summary of Safety and Effectiveness

**Submitter:** Biomet, Inc.  
Airport Industrial Park  
P.O. Box 587  
Warsaw, IN 46581-0587

**Contact Person:** Mary L. Verstynen

**Product Code:** MAI

**Device Name:** LactoSorb® Screw Anchor

### INDICATIONS

Indications for the LactoSorb® Screw Anchors include use in soft tissue reattachment procedures in the shoulder, wrist, and elbow.

#### **3.5mm LactoSorb® Screw Anchor:**

Wrist Indications: Scapholunate ligament reconstruction.

#### **5.5mm LactoSorb® Screw Anchor:**

Shoulder Indications: Bankart repair, SLAP lesion repair, acromioclavicular separation repair, rotator cuff repair, capsule repair, and capsulolabral reconstruction, biceps tenodesis, deltoid repair.

Wrist Indications: Scapholunate ligament reconstruction.

Elbow Indications: Biceps tendon reattachment, ulnar or radial collateral ligament reconstruction.

### DEVICE DESCRIPTION

The LactoSorb® Screw Anchors are resorbable suture anchors used to reattach soft tissue to bone. The anchors consist of a screw portion and a head portion. The screw portion engages the bone while the head portion provides a means to drive the anchor into the bone. The anchors are available in two diameter sizes, 3.5mm and a 5.5mm. Both anchors have an eyelet through the head of the anchor to allow suture to be passed through. They are preloaded onto a driving mechanism to aid in the insertion of the device. Each sterile package contains an anchor preloaded on a driver with suture and needles.

Instrumentation is provided for proper use of the devices. The drill guide aids in arthroscopic placement of the anchor and allows for easy passage into the body. The taps are device size specific to each of the two anchors. The taps are designed to make a

threaded socket into the bone without the use of a separate drill and tap operation. Once the socket is prepared, the anchor can easily be screwed into place..

The LactoSorb® Screw Anchors are made of bioresorbable and biocompatible polymers that have been used in surgical procedures for years. LactoSorb® resorbable copolymer is synthetic polyester derived from lactic and glycolic acids. Polylactic/polyglycolic acid copolymer degrades and resorbs *in vivo* by hydrolysis to lactic and glycolic acids, which are then metabolized by the body. The LactoSorb® material has been found in animal and clinical studies to be biocompatible in both soft tissue and bone tissue.

**Predicate Devices:**

The LactoSorb® Screw Anchor is substantially equivalent to the following:

1. Harpoon Suture Anchors (Arthrotek, Inc., Warsaw, IN)  
510(K) K973775
2. LactoSorb® Suture Anchor (Arthrotek, Inc., Warsaw, IN)  
510(K) K954443



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

JAN 11 2001

Ms. Mary L. Verstynen  
Manager of Clinical Affairs  
Biomet Inc.  
P.O. Box 587  
Warsaw, Indiana 46581

Re: K003273

Trade Name: LactoSorb® Screw Anchor  
Regulatory Class: II  
Product Code: MAI  
Dated: October 17, 2000  
Received: October 18, 2000

Dear Ms. Verstynen:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

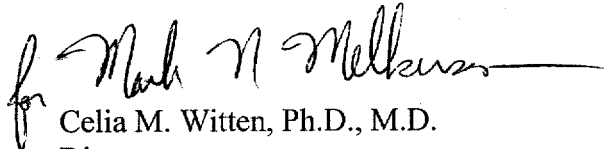
If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the current Good Manufacturing Practice requirement, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic (QS) inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

Page 2 - Ms. Mary L. Verstynen

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4659. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or at (301) 443-6597, or at its Internet address "<http://www.fda.gov/cdrh/dsmamain.html>".

Sincerely yours,

A handwritten signature in black ink, appearing to read "for Mark N. Melkerson", with a long horizontal flourish extending to the right.

Celia M. Witten, Ph.D., M.D.

Director

Division of General, Restorative and

Neurological Devices

Office of Device Evaluation

Center for Devices and

Radiological Health

Enclosure

510(k) NUMBER (IF KNOWN): K003273

DEVICE NAME: LactoSorb® Screw Anchor

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Wrist Indications: Scapholunate ligament reconstruction.

Elbow Indications: Biceps tendon reattachment, ulnar or radial collateral ligament reconstruction.

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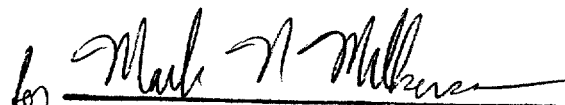
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Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use \_\_\_\_\_  
(Per 21 CFR 801.109)

OR

Over-The-Counter-Use \_\_\_\_\_  
(Optional Format 1-2-96)

for   
(Division Sign-Off)  
Division of General Restora  
510(k) Number K 003273